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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,908	09/12/2003	Tonja Lynn Andreana	PC25095A	6368
28880	7590	11/22/2006	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 11/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/660,908	<b>Applicant(s)</b> ANDREANA ET AL.	
	<b>Examiner</b> Emily Bernhardt	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,13-16,31 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,13,31 and 49-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

In view of applicants' response filed on 9/15/06 the following still applies.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8,13,31,49,50 and new 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard for reasons of record. It is noted that new claims 51-53 are drawn to the sole species remaining in claim 8 but also covers all pharmaceutically acceptable salts. Thus there are 2 species essentially remaining in the present claims with difference in scope being particular salt forms which are also taught by Howard. Applicants have presented a comparative showing for instant compounds labelled "1" and "2" which respectively correspond to claim 8 (and 51) and 49 (and 50). The closest compound in Howard for testing against these species is eg.51 which was tested by applicants. It appears from the articles provided that an atypical antipsychotic will have a higher affinity for binding to the 5-HT<sub>2</sub> receptor than the D-2 and the ratio of such binding is a predictable marker for determining a potential atypical drug. While the ratios presented by applicants are inverted to that reported in the journal articles which

additionally employ pKi values, the outcome appears to be the same, namely that instant compounds 1 and 2 have a markedly higher affinity for the 5-HT<sub>2</sub> vs D-2 receptor than does eg.51. However a question remains- does having a ratio of 60 (or 200) vs 4.3 for prior art compound really result in an unexpectedly better antipsychotic? It would appear Howard's ratio would also put compound of eg.51 in the Atypical list reported by Meltzer (1989 article).

In addition, the data cannot be accorded legal weight as it has not been properly attested to as required. See MPEP 716. Also note Ex parte Gelles, 22 USPQ 2nd, 1318 who stresses that differences in test results should be clearly shown as unexpected, unobvious and of both statistical and practical significance .

**If timely presented in verified form such a Declaration would be considered after final.**

The provisional obviousness-type double remains for all pending claims over claims of copending Application No. 10/660908 for reasons of record. Applicants do not traverse this rejection but only indicate that a terminal disclaimer will not be filed at this time. PTO records indicate that the copending case is still pending.

Method claims 14-16 remain withdrawn. Rejoinder after final is not a matter of right where additional issues may be raised. However, in view of the narrowing of uses in these claims the examiner would rejoin such if compounds claims are otherwise in condition for allowance. However applicants should avoid unclear language. Note, "for example" appearing in claim 14.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt  
Primary Examiner  
Art Unit 1624